sequence No.
Page 1
Appeal Brief

Application/Control No.: 09/944,564
Art Unit: 1623

Examiner: Patrick T. Lewis
Inventor: Nida Nassief

Board of Appeal and Interferences
USPTO
Fax No.:+ 571-273-0053

Appeal Brief submitted further to

Notice of Appeal from the Examiner to the Board of Appeal and Interferences

Submitted in Response to Office Action dated 07/11/2006 (Final Rejection)

Date: December 09, 2006

A- Identification page

Applicant name: Nida Nassief

Application number: 09/944,564

Filling Date of the application: 09/04/2001

Title of the invention: Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils.

The name of the examiner: Patrick T. Lewis

Art unit of the examiner: 1623

Title of the paper: **Appeal Brief**

N. Nassief
Signature
12-10-2006

[redacted]

B- Table of contents

B- Table of contents

	description	Number of pages	Page serial number
A	Identification page	1	1
	USPTO filing receipt	1	2
	Credit card payment form	1	3
B	Table of content page	1	4
C	Real party in interest page	1	5
D	Related appeals and interferences page		5
E	Status of claims pages		5 – 8 added 3 pages of claims
F	Status of amendment pages	XX	9
G	Summary of claimed subject matter	XX	
H	Grounds of rejection to be reviewed on appeal pages	XX	
I	Argument pages	XX	
J	Claim appendix pages	New	
K	Evidence appendix pages	New	
L	Related proceedings pages	1	

Board of Appeal and Interferences
USPTO
Fax No.:+ 571-273-0053

Appeal Brief submitted further to

Notice of Appeal from the Examiner to the Board of Appeal and Interferences

Submitted in Response to Office Action dated 07/11/2006 (Final Rejection)

Date: December 10, 2006

Correction of fax date

The date shown on the fax letter submitted December 10th 2006 is incorrect because the fax machine setting is wrong.

The date shown in my Transmission Verification Report is 10/29/2006 00:28

Actual date is 12/10/2006, local time in Doha-Qatar is 10 PM

Thank you for your effort and excuse my limitations.

Best regards

Sincerely yours

N. Nassief

Nida Nassief

(2)

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/944,564	09/04/2001	1623	1259			24	15

CONFIRMATION NO. 8476

UPDATED FILING RECEIPT

OC000000007223833

AL-JASSIM, Rawaa
2578 River Woods Drive
Naperville, IL 60565

Date Mailed: 12/21/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Nida Abdul-Ghani Nassief, Doha, IRAQ;

Domestic Priority data as claimed by applicant

Foreign Applications

UNITED KINGDOM 9904777.1 03/02/1999

If Required, Foreign Filing License Granted 10/08/2001

Projected Publication Date: 03/28/2002

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils

Preliminary Class

514

sequence No.

Board of Appeal and Interferences
USPTO
Fax No.:+ 571-273-0053

Appeal Brief submitted further to

Notice of Appeal from the Examiner to the Board of Appeal and Interferences

Submitted in Response to Office Action dated 07/11/2006 (Final Rejection)

Date: December 09, 2006

A- Identification page

Applicant name: Nida Nassief

Application number: 09/944,564

Filling Date of the application: 09/04/2001

Title of the invention: Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils.

The name of the examiner: Patrick T. Lewis

Art unit of the examiner: 1623

Title of the paper: **Appeal Brief**

N. Nassief

Signature

12-10-2006

[redacted]

B- Table of contents

1 report page number

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/944,564	09/04/2001	1623	1259			24	15

CONFIRMATION NO. 8476

UPDATED FILING RECEIPT

OC000000007223833

AL-JASSIM, Rawaa
2578 River Woods Drive
Naperville, IL 60565

Date Mailed: 12/21/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Nida Abdul-Ghani Nassief, Doha, IRAQ;

Domestic Priority data as claimed by applicant

Foreign Applications

UNITED KINGDOM 9904777.1 03/02/1999

If Required, Foreign Filing License Granted 10/06/2001

Projected Publication Date: 03/28/2002

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils

Preliminary Class

514

12/28/2001 16:05 16303559624 SAAD ALADHAMI PAGE 01

B- Table of contents

	description	Number of pages	Page serial number
A	Identification page	1	1
	USPTO filing receipt	1	2
	Credit card payment form	1	3
B	Table of content page	1	4
C	Real party in interest page	1	5
D	Related appeals and interferences page		5
E	Status of claims pages		5 – 8 added 3 pages of claims
F	Status of amendment pages	XX	9
G	Summary of claimed subject matter	XX	
H	Grounds of rejection to be reviewed on appeal pages	XX	
I	Argument pages	XX	
J	Claim appendix pages	New	
K	Evidence appendix pages	New	
L	Related proceedings pages	1	

Dear Examiner:

Further to the appeal submitted to the Board of Appeal and Interference dated Oct 10th 2006, please find following the Appeal Brief in compliance with 37 CFR 41.37.

I am dissatisfied with the primary examiner's decision of final rejection dated 07/11/2006 of my claim number 25

C- Real party in interest

I am a self supported 57 years old female medical doctor, the applicant, owner, pro se inventor of the US patent application number: 09/944,564.

D- Related appeal and interferences

None, this is my first appeal.

E- Status of claims

A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed is in the following 3 pages.

Pages 6-7: indicate claimed as filed 07-15-2003

Page 8: indicate amended claims as filed 10-24-2003

[redacted]

6 FAX RECEIVED TO:0817038729306 P.1
15-JUL-2003 07:55 FROM:
JUL 16 2003
GROUP 1600

CLAIMS

1. (Currently amended) Use of glycophosphopeptical for the treatment ~~and/or prophylaxis~~ of allergy/asthma for administration to a mammal ~~such as a~~ human in need of such treatment.

2. (Withdrawn)

3. (Original) A Pharmaceutical composition comprises glycophosphopeptical, in any pharmacologically active form at a concentration of the extract which is effective as a Th1 stimulating agent.

4. A Pharmaceutical composition as claimed in claim 3 further comprising an excipient.

5. A method of treatment of diseases caused by type 1 IgE-mediated hypersensitivity reaction comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of glycophosphopeptical.

6. (Currently amended) The claim 4 including a dosage regimen as a characterizing feature, administering to a patient suffering from a chronic disease a short-term therapy of 5-20 days, ~~preferably 5 days~~, of a Th1 stimulating agent, to get a long-term clinical remission of months as a result of selective switching-off of the eosinophilic inflammation.

7. The use of the pure seeds of Nigella sativa for the preparation of an asthma and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with glycophosphopeptical.

8. A Pharmaceutical composition as claimed in claim 6 further comprising an excipient.

9. A medicament as claimed in any preceding claim, which is adapted and/or packaged for periodic administration to said mammal in doses over a period of 5-20 days, preferably 5 days in doses at least once daily up to ten times/day.

10. A medicament as claimed in claim 9, characterized in that each one of said doses comprises up to 2000mgs of said active agent, preferably about 200-1000mgs, of said active agent adapted for oral administration to said mammal in capsules, or tablets, or lozenges, or as a powder, or a suspension, or a syrup

11. (Withdrawn).

12. A kit comprising a medicament as claimed in claim 10 and 11 packaged in separate doses for periodic administration to said mammal such as a human, contains written or printed instructions.

13. The method of claim 5 and 7 is dependent on the fact that interferon is an in vivo Eosinophilic Chemotactic Factor, and that serum interferon and Th1 lymphocytes are controlling the pre-inflammatory phase of allergic reaction.

14. (Withdrawn).

7

Nassief

15. The method of claim 5 and 7 wherein the recommended dose of Th1 lymphocytes stimulating agent is sufficient to selectively switch –off th eosinophilic inflammation in the patient's airway.

16. The method of claim 5 and 6 wherein Th1 lymphocytes stimulating agents, are capable of stimulating T lymphocytes in culture, comparable to Purified Protein Derivative of BCG, as a classical Cell Mediated Immunity stimulating agent.

17. (Withdrawn)

18. A method of treatment of viral respiratory tract infections ~~such as, but not limited to~~ influenza and common cold, ~~other viral infections~~ comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of Th1 stimulating agents.

19. (Withdrawn).

20. (Withdrawn).

21. A method of treatment of crohns disease comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of Th1 stimulating agents in order to stimulate Cell Mediated Immunity.

22. Use of Th1 stimulating agent, for the treatment of crohns disease to be administered to a mammal such as a human in need of such treatment.

23. (Withdrawn).

24. (Withdrawn).

8

CLAIMS

1 – 24. (Withdrawn)

25. (New) A pharmaceutical composition consisting essentially of glycophosphopeptical for oral administration for the treatment of allergy and asthma in dosage and duration which is effective to:

i- Switch-off the airway eosinophilic inflammation.

ii- Reduce mucus secretion.

iii- Reduce symptom scores significantly.

iv- Restore airways patency as measured by Pulmonary Function Test.

26. (New) A pharmaceutical composition of claim 25, to induce a clinical remission and long-term therapeutic effect in a chronically ill patient.

27. (New) A method of treatment of allergy and asthma patients in need of multiple drugs daily, comprising of administering the pharmaceutical composition of claim 25 for a short course of 1-14 days to induce a remission of 3-12 months.

28. (New) A pharmaceutical composition for the treatment of allergy and asthma consisting essentially of the herbal seeds of Nigella sativa to act as a vaccine that is almost identical to Purified Protein Derivative from Bacillus Calmette Guréin:

i- Switch-off the airway eosinophilic inflammation.

ii- Reduce mucus secretion.

iii- Reduce symptom scores significantly.

iv- Restore airways patency as measured by Pulmonary Function Test.

29. (New) A pharmaceutical composition vaccine of claim 28, to induce a clinical remission and long-term therapeutic effect in a chronically ill patient suffering from asthma and allergy.

30. (New) A method of treatment of allergy and asthma patients in need of multiple drugs daily, comprising of administering the pharmaceutical composition of claim 28 for a short course of 1-14 days to induce a remission of 3-12 months.

31. (New) A pharmaceutical composition vaccine from Nigella sativa, to induce a clinical remission and long-term therapeutic effect in patients with Crohn's disease.

32. (New) A method of treatment of Crohn's disease, comprising of administering the pharmaceutical composition vaccine from Nigella sativa for a short course of 1-14 days to induce symptomatic remission.

33. (New) A pharmaceutical composition vaccine from Nigella sativa, to induce a clinical remission and long-term therapeutic effect in patients with influenza and common cold.

34. (New) A method of treatment of influenza and common cold, comprising of administering the pharmaceutical composition vaccine from Nigella sativa for a short course of 1-14 days to induce symptomatic remission.

F- Status of amendments

Status of any amendment filed subsequent to final rejection is as follows:

- The amendment was entered? Reply Yes, date 10-10-2006

- The amendment has been acted upon by the examiner? Reply: No

G- Summary of claimed subject matter

The claimed invention is related to a pharmaceutical composition consisting essentially of glycophosphopeptical that is used for the treatment of allergy and asthma in claim 25 of the patent.

I will separate the subject matter related to asthma from subject matter related to allergy; because in the Examiner Office Action dated 07/11/2006 the use in asthma have been rejected and the use in allergy have been overlooked and forgotten.

For each of the 2 claimed inventions involved in the appeal, I shall refer to the specification by page and line number, and the best method for carrying out the invention (enablement) and results of early clinical testing including: 1- X-ray films, 2- Photographs of microscopical examination of sputum and 3- statistical analysis of improvement in symptom scores.

Please notice that in the Priority Document I have referred to glycophosphopeptical as substance A or drug N as clarified in page 1 line 3 of the priority document.

Asthma

It appears in the patent application in the following pages:

		From		To	
		Page	Line	Page	Line
Patent Application					
	Disclosure of the Invention	7	1	7	12
		10	13	10	19
	Best Mode of Carrying the Invention	11	2	17	3
Priority Document	Advantages	3			
	Indications for the use of substance A	2	7		
	Advantages	3	Full page		
	Abstract	15	8 lines from the abstract		End of the page
	Stage III	19	Last paragraphs	31	Full page
	Stage IV Including photographs	33	Lower half	37	

	of microscopical exam sputum				
Response to Office action dated May 5, 2004 filed August 4, 2004					
	Table of comparison	9	Full page		
	Results of clinical studies	10	Full page	11	Upper half table
	Reduction in Sputum eosinophil graph	20	Full page		

Allergy including allergic rhinitis and rhinosinusitis

		From		To	
		Page	Line	Page	Line
Patent Application					
	Disclosure of the Invention	7	1	7	12
		10	13	10	19
	Best Mode of Carrying the Invention	11	2	17	3
Priority Document					
	Indications for the use of substance A	2	7	2	10
	Abstract	15	First 8 lines from yhe abstract		
	Stage II	17	Last 2 paragraphs	19	Upper half until stage III
	Table of outcome clinical testing OTHER ALLERGIES including allergic conjunctivitis, chronic urticaria, laryngeal oedema	18	Full page		
Response to Office action dated May 5, 2004 filed August 4, 2004					
		7	Full page		
	Results of clinical studies allergic rhinitis	11	Lower half of the page	15	
	X ray photograph	16	Full page		
	Statistical analysis	18	Full page	19	Full page

H- Grounds of rejection to be reviewed on appeal

It is a single ground of rejection related to prior art.

In the Office Action dated 07/11/2006 the Examiner have rejected claim 25 – 27, in pages 3 – 4 point number 7 reads as: Claims 25-27 are rejected under 35 U. S. C. 102(b) as being anticipated by the following prior art:

" Valoracion clinica immunologica de un modificador de la respuesta biologica, AM3, en el tratamiento de la patologia respiratoria infectiosa infantile", Sanchez Palacios A. et. al. Allergol Immunopathos (Madr) (1992), Vol 20 (1), pages 35-39 (Sanchez).

Sanchez discloses the use of Immunoferon (AM3) in the treatment of childhood infectious respiratory pathology. To assess the immunoclinical effectiveness of a biologic response immunomodulator, glycophosphopeptide (AM3) was administered to 20 children with asthmatic bronchitis. The children received 2 envelops (1gm) daily for 4 months. The clinical and immunological parameters assessed were: cough, dyspnoea, expectoration, frequency and intensity of bronchospasm, time of administration of the symptomatic medication, and the delayed cutaneious cells response by means of the intradermal reaction of 5 antigens: Immunoferon reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication.

Point number 8 reads as: Aplicant's argument filed April 12, 2006 has been fully considered but they are not persuasive. Applicant's argue that Sanchez is referring to infectious respiratory pathology (asthmatic bronchitis) which is not bronchial asthma which is allergic or atopic.

Applicant's arguments have been considered but are not deemed germane. Sanchez teaches the use of glycophosphopeptide for treating asthmatic bronchitis. It was well known in the art at the time of the invention that asthmatic bronchitis is a condition in which the airways in the lung are obstructed due to both persistent asthma and bronchitis. Thus, the patient population treated by the method of Sanchez embraces asthma patients and therefore meets the limitation of the instantly claimed invention.

I- Argument

The following argument have been filed dated October 10, 2006 and is entered in the patent application report. It includes a copied chapter from a medical textbook that will help very much in clarifying the dispute.

Appeal filed October 10, 2006 page 2 reads as:

In this appeal Brief, may I kindly request the Board of Appeal to consider the following two requests:

First: I am still arguing that asthma and asthmatic bronchitis are two separate unrelated diseases and that my claim rejection was brought up by confusion in the name between the old term of asthmatic bronchitis and asthma. Accordingly the use of glycophosphopeptical in the treatment of asthma in my patent is novel and kindly requesting its allowance.

Second: Claim 25 reads as "A pharmaceutical composition consisting essentially of glycophosphopeptical for oral administration for the treatment of allergy and asthma ....etc", I am arguing that the pharmaceutical composition for the treatment of "allergy" as a group of diseases referred to separately in the patent application, under description of the invention, with enabelment and previous clarification in my reply to the Office Action filed on Aug 2004 with X-ray films clarifying its unique outcome of early clinical testing , and will be detailed later, have been forgotten and overlooked. May I kindly request the allowance of this claimed invention.

Asthma is currently an international enigma with increasing incidence and uncontrolled patients. According to medical reports released during 2006 from the "Global Initiative Of Asthma" that will be included in the mail copy of this Response and Appeal.

Appeal filed October 10, 2006Last paragraph page 2 – 2 paragraphs from page 3) reads as:

My argument filed April 12, 2006 was that the Sanchez had excluded cases of asthma in patients selection as described in page 36 column 1 of the article as follows:

"MATERIAL Y METODOS

Pacientes. Se seleccionaron 40 ninos **no atopicos** con clinica respirotoria infecciosa de bronquuitis espastica y/o asmatica con pruebas **cutaneas a neumoallergenos negative** e **IgE total normal.**

May I **add** to my argument filed April 12, 2006 that referring to the title of the article by Sanchez which reads as " Valoracion clinica immunologica de un modificador de la respuesta biologica, AM3, en el tratamiento de la **patologia respiratoria infectiosa infantile",** this description fits the condition of asthmatic bronchitis "bronchiolitis" as will follow, but not asthma.

In the Examiners Office Action dated 07/11/2006, page 4, line 7, he have the following comment "It was well known in the art at the time of the invention that asthmatic bronchitis is a condition in which the airways in the lungs are obstructed due to both persistent asthma and bronchitis."

In the Examiners Office Action dated 07/11/2006, page 4, line 7, he have the following comment "It was well known in the art at the time of the invention that asthmatic bronchitis is a condition in which the airways in the lungs are obstructed due to both persistent asthma and bronchitis."

My reply is that "The term bronchiolitis was first used by Engle and Newns in 1940, bronchiolitis appears to have been born from a long lineage of confusing sobriquets, including "asthmatic bronchitis." As will be described below under the title "Bronchiolitis" page 5 of this report. Therefore at the time of filing my invention it was well known that asthma and asthmatic bronchitis are two separate diseases.

Bronchiolitis (Asthmatic Bronchitis) (page 4 appeal filed October 10, 2006)

Exact definition of asthmatic bronchitis is available from a textbook of "Principles and Practice of Infectious Diseases", selected paragraphs follows indicates that we are dealing with two separate diseases that may coexist in an infant, The following statements contitute a reply to the point raised by the examiner::

Page 812, coloumn 2: "Bronchiolitis is an acute viral lower respiratory tract illness that occurs during the first 2 years of life. **The illness also has been called "wheezy bronchitis" and "asthmatic bronchitis". Whatever term is applied, the syndrome is caused primarily by viral infections. The characteristic clinical manifestations include an acute onset of wheezing and hyperinflation, most commonly associated with cough,** rhinorrhea, tachypnoea (increased respiratory rate) and respiratory distress."

"The term bronchiolitis appears to have been born from a long lineage of confusing sobriquets, including "acute catarrhal bronchitis," "interstitial bronchopneumonia," "spastic bronchopneumonia," "capillary or obstructive bronchiolitis," and "asthmatic bronchitis." Bronchiolitis, however, did not become recognized as a distinct entity until the 1940s."

In page 814, coloumn 1 under the term Pathophysiology **"The term bronchiolitis was first used by Engle and Newns in 1940** for the lower respiratory tract disease observed in young infants that tend to be sever and often fatal. The virus initially replicates in the epithelium of the upper respiratory tract, but in the young infant it tend to spread rapidly to the lower tract airways."

"Inflammatory changes of various severity are observed in most small bronchi and bronchioles. The inflammation and edema make the small-lumen airways in infants particularly vulnerable to obstruction. Thus, although airflow is impended during both inspiration and expiration, the latter is more affected and prolonged."

In the first column, last paragraph in page 815, under the title of "Pathophysiology": "Clarifying the relationship between bronchiolitis and subsequent asthma is complicated by confusion about the Pathophysiology of asthma itself".....Nevertheless, **"The association between bronchiolitis and asthma is not straightforward. Several investigatorshave demonstrated that children with bronchiolitis in infancy have no increased risk for asthma** or abnormal pulmonary function by the time they reach early adolescence.

In the first column of page 816 under the title "Diagnosis" and its continuation in the second column in the same page: "The diagnosis of bronchiolitis is made most frequently on the basis of the characteristic clinical and epidemiological findings. However considerable confusions exist over the exact definition of bronchiolitis. A variety of entities may cause a similar picture of dyspnoea and wheezing in the infant. Asthma is not easily differentiated, particularly if it is the infant's first episode. **Furthermore the two diseases may be combined."**

Annex III. Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

Appeal filed October 10, 2006 page 2 paragraph 3 and down - page 3) reads as:

Most important, to support my argument further, I am submitting new evidence from the standard teaching of medical textbooks that clarifies the point that asthma previously was used to indicate "shortness of breath" as in the case of the term "**cardiac asthma**" that is used to denote shortness of breath in heart failure (Annex II). Furthermore the correlation between asthma and asthmatic bronchitis; selected from the textbook of Principles and Practice of Infectious Diseases 2005 (Annex III), asthmatic bronchitis is currently named bronchiolitis. The term bronchiolitis was first used by Engle and Newns in 1940 for the lower respiratory tract disease observed in young infants. The term bronchiolitis appears to have been born from a long lineage of confusing sobriquets, including "acute catarrhal bronchitis," "interstitial bronchopneumonia," "spastic bronchopneumonia," "capillary or obstructive bronchiolitis," and "asthmatic bronchitis." And that "We are dealing with two separate diseases that may coexist in an infant, and that children with bronchiolitis in infancy have no increased risk of asthma by the time they reach adolescence." This will be detailed further in the following text. May I kindly request consideration of this new evidence and other reference in the text and allow my claimed invention.

Confusing medical terms using asthma

The term asthma, historically, is used to designate any disease characterized by "asthma-like symptoms", in patients complaining of dyspnoea, wheeze, cough and sputum. Those diseases are unrelated to the disease entity of current asthma; examples are 1- "cardiac asthma" and 2- "asthmatic bronchitis".

1- Cardiac Asthma

The clinical manifestations of heart failure includes respiratory disturbances as dyspnoea and paroxysmal nocturnal dyspnoea; this term refers to attacks of sever shortness of breath and coughing that generally occur at night. Cardiac asthma is closely related to paroxysmal nocturnal dyspnoea and nocturnal cough and is characterized by wheezing secondary to bronchospasm-most prominent at night.

Annex II - Part VIII Disorders of the Cardiovascular System: page 1370. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE. 16th Edition (2005) Mc Graw-Hill

J- Claim appendix

In the Office Action dated 07/11/2006 the Examiner have rejected claim 25 - 27 of my patent application number 09/944,564. Currently I am defending claim 25 that reads as follows:

25. A pharmaceutical composition consisting essentially of glycophosphopeptical for oral administration for the treatment of allergy and asthma in dosage and duration which is effective to:

i- Switch-off the airway eosinophilic inflammation.

ii- Reduce mucus secretion.

iii- Reduce symptom score significantly.

iv- Restore airway patency as measured by Pulmonary Function test.

L- Related proceedings appendix

None

This is the first appeal submitted

Evidence will be sent by mail

END OF REPORT

K- Evidence appendix

An appendix containing copies of any evidence submitted pursuant to $$ 1.130, 1.131 or 1.132 of this title or any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See $ 41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

1- " Valoracion clinica immunologica de un modificador de la respuesta biologica, AM3, en el tratamiento de la patologia respiratoria infectiosa infantile", Sanchez Palacios A. et. al. Allergol Immunopathos (Madr) (1992), Vol 20 (1), pages 35-39 (Sanchez).

2- Annex II - Part VIII Disorders of the Cardiovascular System: page 1370. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE. 16th Edition (2005) Mc Graw-Hill

3- Annex III. Caroline Breese Hall and John T. McBride. Bronchiolitis. Chapter 60: 812-819. PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES. Sixth Edition 2005. Elsevier Churchill Livingstone.

4- Annex 1

Board of Appeal and Interferences
USPTO
Fax No.:+ 571-273-0053

Appeal Brief submitted further to

Notice of Appeal from the Examiner to the Board of Appeal and Interferences

Submitted in Response to Office Action dated 07/11/2006 (Final Rejection)

Date: December 09, 2006

A- Identification page

Applicant name: Nida Nassief

Application number: 09/944,564

Filling Date of the application: 09/04/2001

Title of the invention: Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils.

The name of the examiner: Patrick T. Lewis

Art unit of the examiner: 1623

Title of the paper: **Appeal Brief**

N. Nassief

Signature

12-10-2006

[redacted]

B- Table of contents

2

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
WWW.USPTO.GOV

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/944,564	09/04/2001	1623	1259			24	15

CONFIRMATION NO. 8476

UPDATED FILING RECEIPT

OC0000000007223833

AL-JASSIM, Rawaa
2578 River Woods Drive
Naperville, IL 60565

Date Mailed: 12/21/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Nida Abdul-Ghani Nassief, Doha, IRAQ;

Domestic Priority data as claimed by applicant

Foreign Applications

UNITED KINGDOM 9904777.1 03/02/1999

If Required, Foreign Filing License Granted 10/06/2001

Projected Publication Date: 03/28/2002

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils

Preliminary Class

514

Dear Examiner:

Further to the appeal submitted to the Board of Appeal and Interference dated Oct 10th 2006, please find following the Appeal Brief in compliance with 37 CFR 41.37.

I am dissatisfied with the primary examiner's decision of final rejection dated 07/11/2006 of my claim number 25

C- Real party in interest

I am a self supported 57 years old female medical doctor, the applicant, owner, pro se inventor of the US patent application number: 09/944,564.

D- Related appeal and interferences

None, this is my first appeal.

E- Status of claims

A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed is in the following 3 pages.

Pages 6-7: indicate claimed as filed 07-15-2003

Page 8: indicate amended claims as filed 10-24-2003

[redacted]

6 FAX RECEIVED TO:00170387293O6 P.1
JUL 16 2003
15-JUL-2003 07:55 FROM:
GROUP 1600

CLAIMS

1. (Currently amended) Use of glycophosphopeptical for the treatment ~~and/or prophylaxis~~ of allergy/asthma for administration to a mammal ~~such as a~~ human in need of such treatment.

2. (Withdrawn)

3. (Original) A Pharmaceutical composition comprises glycophosphopeptical, in any pharmacologically active form at a concentration of the extract which is effective as a Th1 stimulating agent.

4. A Pharmaceutical composition as claimed in claim 3 further comprising an excipient.

5. A method of treatment of diseases caused by type I IgE-mediated hypersensitivity reaction comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of glycophosphopeptical.

6. (Currently amended) The claim 4 including a dosage regimen as a characterizing feature, administering to a patient suffering from a chronic disease a short-term therapy of 5-20 days, ~~preferably 5 days~~, of a Th1 stimulating agent, to get a long-term clinical remission of months as a result of selective switching-off of the eosinophilic inflammation.

7. The use of the pure seeds of Nigella sativa for the preparation of an asthma and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with glycophosphopeptical.

8. A Pharmaceutical composition as claimed in claim 6 further comprising an excipient.

9. A medicament as claimed in any preceding claim, which is adapted and/or packaged for periodic administration to said mammal in doses over a period of 5-20 days, preferably 5 days in doses at least once daily up to ten times/day.

10. A medicament as claimed in claim 9, characterized in that each one of said doses comprises up to 2000mgs of said active agent, preferably about 200-1000mgs, of said active agent, adapted for oral administration to said mammal in capsules, or tablets, or lozenges, or as a powder, or a suspension, or a syrup

11. (Withdrawn).

12. A kit comprising a medicament as claimed in claim 10 and 11 packaged in separate doses for periodic administration to said mammal such as a human, contains written or printed instructions.

13. The method of claim 5 and 7 is dependent on the fact that interferon is an in vivo Eosinophilic Chemotactic Factor, and that serum interferon and Th1 lymphocytes are controlling the pre-inflammatory phase of allergic reaction.

14. (Withdrawn).

7

15. The method of claim 5 and 7 wherein the recommended dose of Th1 lymphocytes stimulating agent is sufficient to selectively switch –off th eosinophilic inflammation in the patient's airway.

16. The method of claim 5 and 6 wherein Th1 lymphocytes stimulating agents, are capable of stimulating T lymphocytes in culture, comparable to Purified Protein Derivative of BCG, as a classical Cell Mediated Immunity stimulating agent.

17. (Withdrawn)

18. A method of treatment of viral respiratory tract infections ~~such as, but not limited to~~ influenza and common cold, ~~other viral infections~~ comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of Th1 stimulating agents.

19. (Withdrawn).

20. (Withdrawn).

21. A method of treatment of crohns disease comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of Th1 stimulating agents in order to stimulate Cell Mediated Immunity.

22. Use of Th1 stimulating agent, for the treatment of crohns disease to be administered to a mammal such as a human in need of such treatment.

23. (Withdrawn).

24. (Withdrawn).

8

CLAIMS

1 – 24. (Withdrawn)

25. (New) A pharmaceutical composition consisting essentially of glycophosphopeptical for oral administration for the treatment of allergy and asthma in dosage and duration which is effective to:

i- Switch-off the airway eosinophilic inflammation.

ii- Reduce mucus secretion.

iii- Reduce symptom scores significantly.

iv- Restore airways patency as measured by Pulmonary Function Test.

26. (New) A pharmaceutical composition of claim 25, to induce a clinical remission and long-term therapeutic effect in a chronically ill patient.

27. (New) A method of treatment of allergy and asthma patients in need of multiple drugs-daily, comprising-of-administering-the-pharmaceutical composition of claim 25 for a short course of 1-14 days to induce a remission of 3-12 months.

28. (New) A pharmaceutical composition for the treatment of allergy and asthma consisting essentially of the herbal seeds of Nigella sativa to act as a vaccine that is almost identical to Purified Protein Derivative from Bacillus Calmette Gurein:

i- Switch-off the airway eosinophilic inflammation.

ii- Reduce mucus secretion.

iii- Reduce symptom scores significantly.

iv- Restore airways patency as measured by Pulmonary Function Test.

29. (New) A pharmaceutical composition vaccine of claim 28, to induce a clinical remission and long-term therapeutic effect in a chronically ill patient suffering from asthma and allergy.

30. (New) A method of treatment of allergy and asthma patients in need of multiple drugs daily, comprising of administering the pharmaceutical composition of claim 28 for a short course of 1-14 days to induce a remission of 3-12 months.

31. (New) A pharmaceutical composition vaccine from Nigella sativa, to induce a clinical remission and long-term therapeutic effect in patients with Crohn's disease.

32. (New) A method of treatment of Crohn's disease, comprising of administering the pharmaceutical composition vaccine from Nigella sativa for a short course of 1-14 days to induce symptomatic remission.

33. (New) A pharmaceutical composition vaccine from Nigella sativa, to induce a clinical remission and long-term therapeutic effect in patients with influenza and common cold.

34. (New) A method of treatment of influenza and common cold, comprising of administering the pharmaceutical composition vaccine from Nigella sativa for a short course of 1-14 days to induce symptomatic remission.

F- Status of amendments

Status of any amendment filed subsequent to final rejection is as follows:

- The amendment was entered? Reply Yes, date 10-10-2006

- The amendment has been acted upon by the examiner? Reply: No

G- Summary of claimed subject matter

The claimed invention is related to a pharmaceutical composition consisting essentially of glycophosphopeptical that is used for the treatment of allergy and asthma in claim 25 of the patent.

I will separate the subject matter related to asthma from subject matter related to allergy; because in the Examiner Office Action dated 07/11/2006 the use in asthma have been rejected and the use in allergy have been overlooked and forgotten.

For each of the 2 claimed inventions involved in the appeal, I shall refer to the specification by page and line number, and the best method for carrying out the invention (enablement) and results of early clinical testing including: 1- X-ray films, 2- Photographs of microscopical examination of sputum and 3- statistical analysis of improvement in symptom scores.

Please notice that in the Priority Document I have referred to glycophosphopeptical as substance A or drug N as clarified in page 1 line 3 of the priority document.

Asthma

It appears in the patent application in the following pages:

		From		To	
		Page	Line	Page	Line
Patent Application					
	Disclosure of the Invention	7	1	7	12
		10	13	10	19
	Best Mode of Carrying the Invention	11	2	17	3
Priority Document	Advantages	3			
	Indications for the use of substance A	2	7		
	Advantages	3	Full page		
	Abstract	15	8 lines from the abstract		End of the page
	Stage III	19	Last paragraphs	31	Full page
	Stage IV Including photographs	33	Lower half	37	

	of microscopical exam sputum				
Response to Office action dated May 5, 2004 filed August 4, 2004					
	Table of comparison	9	Full page		
	Results of clinical studies	10	Full page	11	Upper half table
	Reduction in Sputum eosinophil graph	20	Full page		

Allergy including allergic rhinitis and rhinosinusitis

		From		To	
		Page	Line	Page	Line
Patent Application					
	Disclosure of the Invention	7	1	7	12
		10	13	10	19
	Best Mode of Carrying the Invention	11	2	17	3
Priority Document					
	Indications for the use of substance A	2	7	2	10
	Abstract	15	First 8 lines from yhe abstract		
	Stage II	17	Last 2 paragraphs	19	Upper half until stage III
	Table of outcome clinical testing OTHER ALLERGIES including allergic conjunctivitis, chronic urticaria, laryngeal oedema	18	Full page		
Response to Office action dated May 5, 2004 filed August 4, 2004					
		7	Full page		
	Results of clinical studies allergic rhinitis	11	Lower half of the page	15	
	X ray photograph	16	Full page		
	Statistical analysis	18	Full page	19	Full page

B- Table of contents

1 report page number

2

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/944,564	09/04/2001	1623	1259			24	15

CONFIRMATION NO. 8476

UPDATED FILING RECEIPT

OC000000007223833

AL-JASSIM, Rawaa
2578 River Woods Drive
Naperville, IL 60565

Date Mailed: 12/21/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Nida Abdul-Ghani Nassief, Doha, IRAQ;

Domestic Priority data as claimed by applicant

Foreign Applications

UNITED KINGDOM 9904777.1 03/02/1999

If Required, Foreign Filing License Granted 10/06/2001

Projected Publication Date: 03/28/2002

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils

Preliminary Class